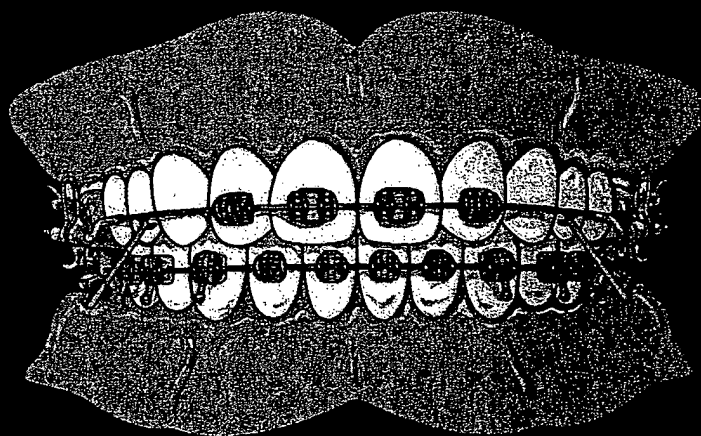


Orthodontics and Dentofacial Orthopedics

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Chapter 27

INVISIBLE RETAINERS AND ALIGNERS

The most versatile of all retainers used in our practice is the invisible retainer (Fig. 27-1), often termed "invisibles." This type of thin acrylic retainer was developed originally by Henry Nahoum in the late 1950s, and an article on this subject (unknown to us until very recently) was published in the *New York State Dental Journal* in 1964.¹

The invisible retainer, as we use them, was developed by Robert Ponitz of Ann Arbor, Michigan.² Typically this retainer is formed from a sheet of thin Biocryl™ or other similar material that is heated and forced by suction^{1,2} or pressure³ on to a work model of the dentition.

This type of retainer has many uses in routine orthodontic practice, not only as a finishing and retention appliance, but also as an active treatment adjunct. The development of the Invisalign® System of aligners for comprehensive movement, a logical outgrowth of this technology, will be discussed later in this chapter.

FUNCTIONS OF INVISIBLE RETAINERS

The invisible retainer can be used for three purposes: minor tooth movement, long-term retention, and as a transitional retainer.

Minor Tooth Movement

Invisible retainers can produce minor tooth movements effectively, whether used immediately after debonding, after positioner wear is concluded, or in instances of

minor relapse during the retention period. When used after the end of active fixed appliance treatment, even though the vast majority of dental irregularities have been eliminated, small inter-arch and intra-arch discrepancies often remain in the treated occlusion. Fine detailing of the occlusion can be accomplished by resetting up to one tooth per quadrant in the work model prior to invisible retainer fabrication.

Small adjustments in tooth position (e.g., tipping, rotation, intrusion) can be achieved most easily for incisors and premolars, due to the morphology of these teeth. For example, a slightly rotated lower incisor can be reset into an ideal relationship before fabricating the appliance. The elasticity of the acrylic used in the fabrication of the invisible retainer can help force the rotated tooth into a new, aligned position.

Conical shaped teeth (e.g., some canines) are more difficult to reposition with an invisible retainer. Although simple tipping movements are accomplished easily as is minor tooth intrusion, the correction of rotations is more difficult. Extrusive movements are difficult to produce in all teeth, except if significant undercuts are present.

Only very minor changes in the position of the molars should be attempted with conventional invisible retainers. Occasionally, a remaining band space can be closed by repositioning the molar more anteriorly; however, gross changes in the position of the molar usually are not possible, because the invisible retainer simply will not fit on the patient's dental arch with the molar in its new position. In addition, it should be noted that adjacent teeth (e.g., both maxillary central incisors) typically cannot be repositioned simultaneously with a conven-

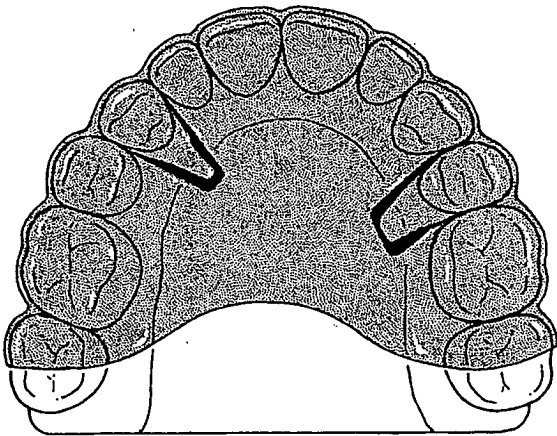


Figure 27-1. Maxillary invisible retainer. Note that the posterior extension is contoured to prevent evoking the patient's gag reflex. Alternatively, the invisible can be trimmed so that all or part of the palate is left uncovered.

tional invisible retainer, because the retainer will not snap into place at the time of delivery.

Usually a set of invisible retainers is worn for one or two months before a new set of retainers is made. The number of sets of retainers necessary, is, of course, dependent on the quality of the orthodontic result at the time of debonding. If multiple teeth have to be reset in a quadrant, multiple sets of invisibles will be necessary.

Long-term Retention

The second function of the invisible retainer is to stabilize the dentition in its current position. Invisible retainers are used as a long-term retention appliance after minor tooth movements have been achieved. These acrylic retainers usually will last for six to twelve months or longer, depending on the parafunctional activities of the patient. Some patients use these retainers indefinitely, whereas the invisible retainers of others (especially heavy bruxers) show a high degree of wear and/or breakage. In the latter case, wire and acrylic retainers (e.g., Hawley retainer, circumferential retainer) can be used effectively.

Many clinicians are concerned about using any retainer that provides occlusal coverage. It has been our experience that, in general, the occlusal coverage provided by the invisible retainer does not appear to pose many clinical problems. The patient usually "self-equilibrates" the maxillary and mandibular appliances within a few days, and symptoms of temporomandibular joint disorders are rare. As with any removable appliance, patients are instructed to discontinue invisible re-

tainer wear if any problems with their temporomandibular joints are encountered. Also, if a patient has chronically poor oral hygiene, decalcification under the retainer may occur. Patients should be instructed to brush their teeth prior to the insertion of invisible retainers.

One of the major advantages of the invisible retainer is that it provides a positive positioning of the teeth, thus aiding in the prevention of relapse. This is particularly true with the position of the incisors, specifically the mandibular incisors and the maxillary lateral incisors. Using many types of conventional wire retainers, minor changes in tooth position often are observed; this is not the case when invisible retainers are worn as directed. In addition, if the invisible retainers are not worn for some time, resuming retainer wear on a fulltime basis should eliminate minor undesirable changes in tooth position.

Invisible retainers can be used for minor space closure or perhaps, better stated, for space reallocation. For example, a small diastema between the maxillary central incisors may be closed by repositioning one of the central incisors. The angulation of one of the incisors may be altered, or alternatively the space may be relocated to another part of the dental arch. After several invisible retainers have been fabricated, bonding material may be placed at the distal of the lateral incisors to ensure that the midline diastema does not reopen.

If a patient has significant interproximal spacing at the end of treatment, the use of invisible retainers is contraindicated, as no space closure is possible with traditional invisible retainers. Prior finishing with a positioner is advisable. If a positioner is not used, a retainer such as a circumferential retainer is recommended.

Transitional Appliance

As mentioned elsewhere in this book, the invisible retainer also can be used as a transitional appliance between phases of orthodontic treatment. If, for example, incisor intrusion and protrusion have been accomplished successfully prior to the fabrication of a functional appliance, the invisible retainer is used as a transitional retainer until fulltime functional appliance wear has been achieved.

Generally, the transitional retainer should be used without the resetting of any teeth. Even though minor irregularities may remain, changing the position of certain teeth while a functional appliance is being fabricated may lead to problems with the fit of the functional appliance. This is particularly true if an acrylic splint Herbst appliance is used, because of the precise reproduction of the anatomy of the teeth in this type of appliance.

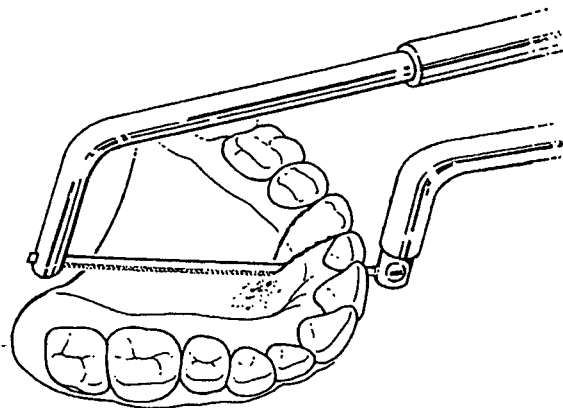


Figure 27-2. A laboratory saw is used to remove the canine from the model. Note the tapered cuts.

Another common use of the conventional invisible retainer as a transitional appliance is in the adolescent patient who is to receive a dental implant after active craniofacial growth has ceased. In this situation, a pontic may be incorporated into the invisible, or alternatively, an invisible retainer can be fabricated over a flipper to which a pontic is attached. The pontic holds the space that was established for the implant during orthodontic treatment. The invisible retainer with the pontic is worn until implant replacement of the missing tooth has been completed.

FABRICATION OF INVISIBLE RETAINERS

The steps in invisible retainer fabrication have been described previously by McNamara and co-workers³ in the *Journal of Clinical Orthodontics*. This article is updated below. In this summary, the possibilities of making minor changes in tooth position with invisible retainers will be stressed.

Preparation of the Work Models

Upper and lower alginate impressions are made with standard aluminum trays, and a wax bite registration is obtained in centric occlusion to articulate the models, if the correct occlusion is not obvious. The impressions are poured in plaster and trimmed as standard work models with minimal base (Fig. 27-2). Before articulating the maxillary and mandibular work models, excess plaster and any bubbles on the articulating surfaces of the teeth should be removed carefully with a laboratory knife or waxing instrument.

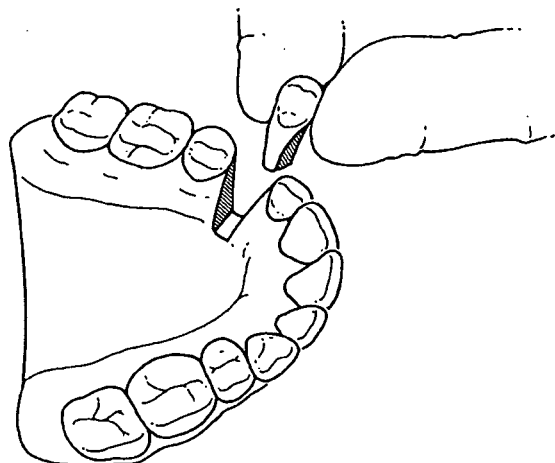


Figure 27-3. Finger pressure or a laboratory knife is used to break the remaining plaster, freeing the tooth. The cut in the stone is trimmed so that the tooth can be repositioned, allowing enough space for wax.

The orthodontist then checks the hand articulated models for resets by placing the models together in centric occlusion. The teeth to be reset are indicated on the laboratory slip, with specific instructions as to the direction of movement or the percentage of rotation, if necessary.

Minor Tooth Repositioning on Work Models

One of the limitations of using a conventional invisible retainer as a tooth-moving device, in contrast to the series of aligners to be discussed later, is that in order to insure appliance fit, usually only one tooth per quadrant can be reset in each retainer. In the four premolar extraction case used as an example (Fig. 27-2), it is necessary to reposition the maxillary right canine. Interdental cuts that approximate the long axis of the tooth are made on the maxillary work model with a laboratory saw. Gentle finger pressure is used to fracture the remaining plaster and free the tooth from the model (Fig. 27-3).

A laboratory knife is used to trim the area of the model in which the tooth is to be repositioned. Stone also must be removed from the sides of the "extracted" tooth (Fig. 27-4) to allow repositioning of this tooth in a more ideal position. Medium-hard pink wax is melted and placed into the area where the tooth has been removed (Fig. 27-5), and the tooth is repositioned temporarily in the wax (Fig. 27-6).

In this example the lower premolar also needs repositioning; it is removed from the mandibular work

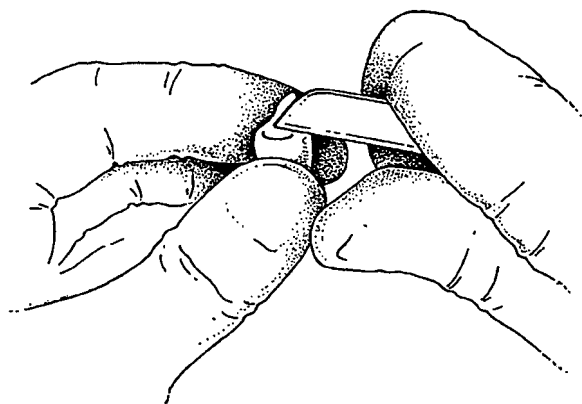


Figure 27-4. Tooth trimmed with laboratory knife.

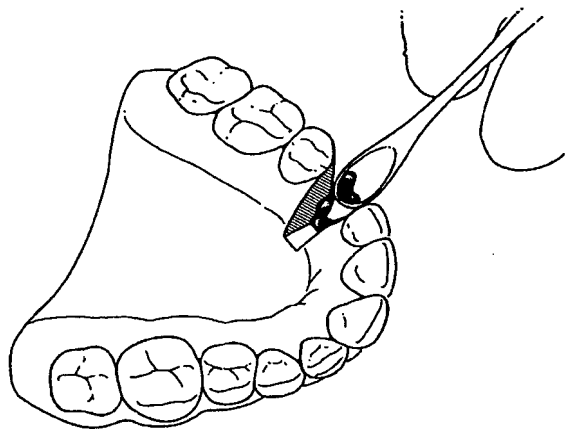


Figure 27-5. Melted wax placed in tooth space.

model in a similar manner. The dental casts are occluded, and the final changes in tooth position are achieved. The wax contours are smoothed, and the models are ready for retainer fabrication (Fig. 27-7). If interproximal undercuts are present, particularly in adult patients, they should be eliminated with wax. Similarly, any missing teeth that are not being replaced with a pontic should be waxed out as well.

Application of Acrylic

The invisible retainers are formed from 1 mm thick acrylic by means of a Biostar™ positive pressure thermal forming machine (Great Lakes Orthodontic Products, Tonawanda, NY). Splint Biocryl™ is used for maxillary retainers because of its transparency. Invisacryl C™, also available through Great Lakes Orthodontics, is used for the fabrication of mandibular retainers because of its durability.

The work model is placed into the large (125 mm) model holder of the Biostar™, with the occlusal plane horizontal. Lead pellets are placed around the model to a point 1 mm below the desired margin of the appliance. The holding frame is placed on the pressure chamber, with the gasket and the four holding pins facing upward. A piece of 1 mm acrylic is placed inside the four pins of the holding frame, and acrylic is secured in position by placing the clamping frame over the holding frame. The handle of the clamping frame is turned to the left and secured with light pressure to lock it in place.

The heating element is moved into position over the pressure chamber and left in place for 25-30 seconds for splint Biocryl™ and 80 seconds for Invisacryl C™ to soften the acrylic. The heating element is removed, the pressure chamber is rotated over the model holder, and the pressure chamber handle is engaged. Air pressure, rather than partial vacuum pressure as originally advocated by Ponitz,¹ is used to push the softened Biocryl™ onto the work model at about five atmospheres of pressure.

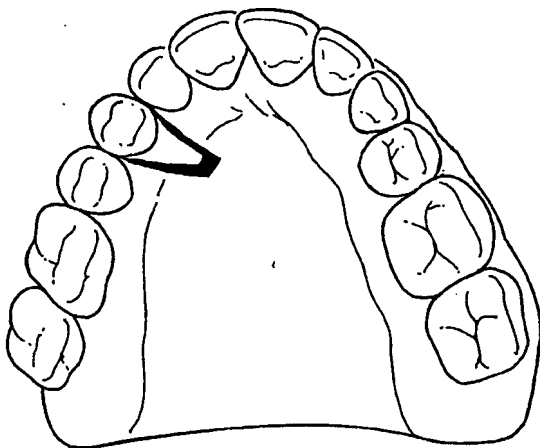


Figure 27-6. Tooth secured in preliminary corrected position.

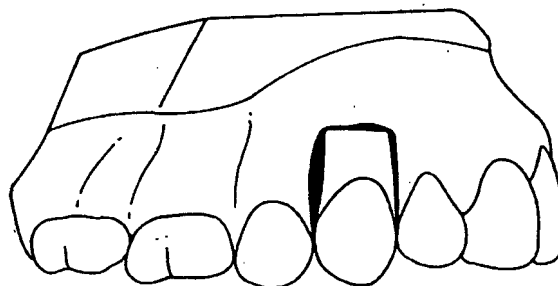


Figure 27-7. After the occlusion has been checked and the tooth is properly positioned, the wax is smoothed to a final contour.

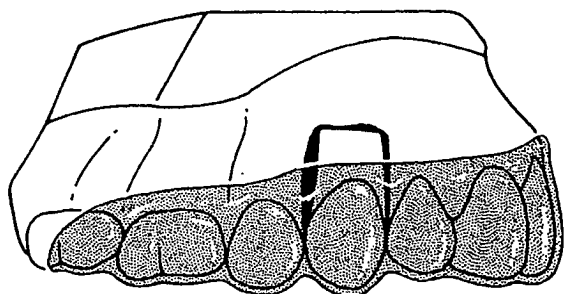


Figure 27-8. Finished trim of the maxillary invisible retainer. Care should be taken not to encroach on the gingival margin.

Trimming of Acrylic

After two minutes, the pressure chamber handle is unlocked and the pressure chamber is rotated out of position. The clamping frame is removed and the acrylic with the embedded work model is taken off the Bio-star™. The work model is removed from the acrylic with a laboratory knife, destroying the model. Excess acrylic is trimmed with a sturdy pair of scissors, and the general contour of the invisible retainer is established with a carborundum disk. The invisible is soaked in warm (not hot) water to eliminate the wax.

A pair of scissors is used for the final trimming and finishing of the appliance. No further polishing or trimming usually is necessary, although a light sanding, pumicing, or polishing of the edges of the appliance may be required in some instances.

It is extremely important always to cover at least part of the last molar in each arch (including third molars) to prevent extrusion of these teeth with full-time appliance wear. The invisible retainer usually is

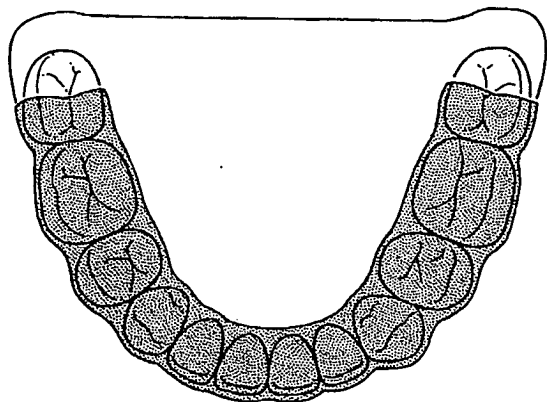


Figure 27-9. Finished contour of mandibular invisible retainer. Note that at least part of the last tooth is incorporated into the retainer bilaterally.

trimmed to include full palatal coverage (Fig. 27-1), although all or part of the palate can be removed, if necessary. The facial surface is trimmed to follow the approximate contour of the gingival margin (Fig. 27-8).

The mandibular invisible retainer is trimmed in a horseshoe shape, again covering part of the last molar (Fig. 27-9). The facial and lingual surfaces are trimmed to approximate the gingival margins (Fig. 27-10). Invisible retainers require virtually no adjustment at the time of delivery, except for trimming with scissors in areas of soft tissue impingement. Often invisible retainers can be mailed to the patient with instructions to trim the acrylic at any point at which irritation occurs.

If teeth have been reset in the invisible retainer, the patient should be told that the appliance will take a few hours to a few days to seat completely. If too much tooth movement has been carried out on the work model or more than one tooth per quadrant has been reset substantially, the appliance will not fit and will have to be remade.

If a pontic is to be incorporated into an invisible retainer, the size and the appropriate shade are determined at chairside. After the correct pontic is obtained, it is trimmed to fit the available space on the work model, and then it is positioned on the cast with medium hard pink wax. The invisible retainer is fabricated as usual. As a final step, the pontic is glued to the invisible with an adhesive (e.g., MDS Adhesive™, Great Lakes Orthodontic Products, Tonawanda NY), letting the adhesive dry thoroughly before delivery.

NEW TECHNOLOGY: The Invisalign® System

One of several new treatment approaches presented in this text is the methodology developed by Align Technology (Santa Clara CA). The Invisalign® System is a technologically advanced esthetic approach to treating

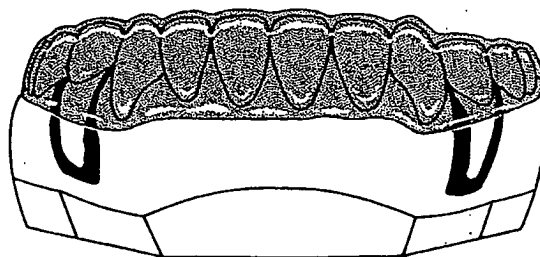


Figure 27-10. Final contour of the mandibular retainer. Typically the gingival margin is not scalloped, but rather forms gentle curves.

malocclusion. This approach brings the concept of the invisible retainer into the 21st century by linking these relatively simple and easy to fabricate retainers (Figs. 27-11 and 27-12) with three-dimensional graphic imaging and CAD/CAM technology.

The Invisalign® System was introduced commercially in June 1999. At this writing, over half of all U.S. and Canadian orthodontists have been certified to use the Invisalign® System.⁴ During the certification process, the orthodontist becomes familiar with case selection criteria, receives training in poly-vinyl siloxane impression taking, and learns communication skills via the company's treatment planning forms and website.⁵

Methodology

The basic concept of using one or more removable semi-flexible appliances to move teeth is not new, as suggested by the use of tooth positioners⁶ as well as various overlay types of appliances such as invisible retainers.^{1-3,7,8} The amount of tooth movement possible with a traditional invisible retainer, however, is limited. As mentioned earlier, it has been our experience that routinely only one tooth per quadrant can be moved effectively and that moving molars with traditional invisible retainers is very difficult. Because of the 3D graphical imaging and precise computer manipulation of "virtual" models, more precise tooth movements involving a greater number of teeth are possible with the Invisalign® System. This includes tooth movement in the molar region.

A variety of tooth movement options are available, at the discretion of the clinician. For example, dental expansion can be accomplished in several ways. In the first method, all the teeth move at the same time; expansion occurs as teeth move to eliminate the crowding. With the second method, the first premolars through second molars expand first. When space appears distal to the canines, the canines move distally, creating space anteriorly. This latter space can be used to alleviate crowding in the incisor region.

According to current case selection criteria, a candidate for the Invisalign® System should have fully erupted permanent teeth, for whom growth has minimal or no effect on treatment (*i.e.*, late adolescents and adults).⁹ Currently, Align Technology does not include continued craniofacial growth of the patient as a factor within its software.

Occlusal problems that are amenable to Invisalign® orthodontic appliance treatment include mild spacing (1-3 mm), moderate spacing (4-6 mm), mild crowding (1-3), moderate crowding (4-6), narrow arches that are dental in origin (4-6 mm), as well as patients who have relapsed following conventional orthodontic treat-

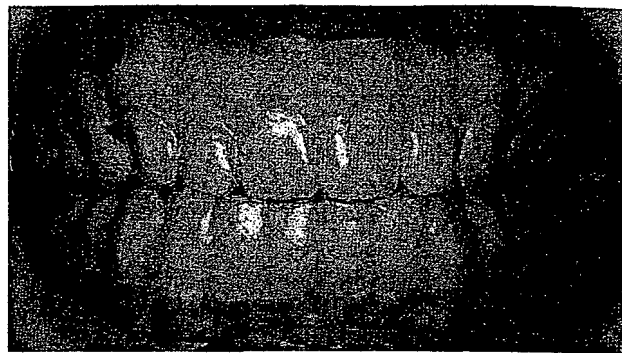


Figure 27-11. Frontal view of the maxillary and mandibular aligners of the Invisalign® System.

ment.⁹ Such treatment decreases the time that the patient is in fixed appliances.

Align Technology reports that orthodontic movements which can be produced effectively with aligners include space closure, tooth movement following interproximal reduction (*i.e.*, stripping), dental (not skeletal/sutural) expansion, flaring, and distalization. In addition, space closure following the extraction of a lower incisor can be produced successfully. The Invisalign® System also can be used in conjunction with fixed appliances (*e.g.*, following an initial phase of treatment with fixed appliances to correct severe tooth rotations and malalignments prior to aligner fabrication).

Clinical studies are underway to evaluate the treatment of more complex orthodontic problems, including premolar extraction treatment, severe deep bite, anteroposterior corrections greater than 2 mm, and up-righting of severely tipped teeth.^{5,11} At present, such treatments do not fall within the criteria for case acceptance by Align Technology, but may be acceptable in the future. Orthodontic problems not expected to become appropriate for the Invisalign® System include skeletal expansion, patients with significant temporomandibular joint pathology, severe anterior or posterior open bites, and tooth impaction/forced eruption problems.¹⁰

Invisalign® Components

The Invisalign® System has a number of components, some familiar to the average orthodontist and some not. The appliances used in the treatment, termed "aligners" (Figs. 27-11 and 27-12), are comparable to the invisible retainers described earlier in this chapter. The aligners are made from a thin (.030") proprietary medical-grade plastic material that is a mixture of plastics comparable to polycarbonate. This material also is similar to the 1 mm thick splint Biocryl™ described earlier.



Figure 27-12. Right lateral view of maxillary and mandibular aligners. The aligners are scalloped to reflect the gingival contours.

The aligners are trimmed at the level of the gingival margin, so that both aligners are of horseshoe shape (Figs. 12-13 and 27-14). Each aligner is worn for a two-week period prior to being replaced by the next aligner in the series. Each aligner covers a patient's teeth fully and is nearly invisible when in place. Aligners typically are worn in pairs, one for each arch. Single arch treatment can be undertaken as well.

The second component of the Invisalign® System is the patented software, the technology that enables the design and manufacture of the aligners. The software includes Treat 2.x® software, which is an in-house manufacturing program that generates a simulated treatment outcome and then a series of intermediate stages of movement from the initial malocclusion to the final treatment result. All manipulations of the occlusion are

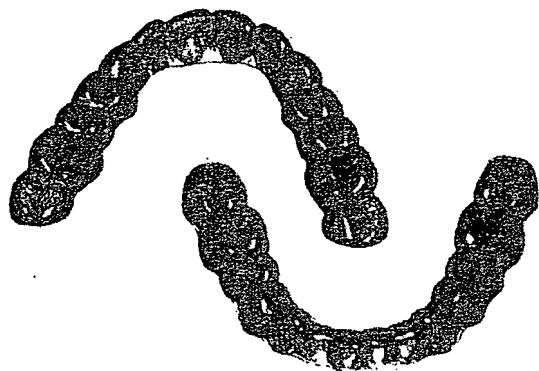


Figure 27-13. Finished contour of maxillary and mandibular aligners. A patient identifier and the series number in the sequence are incorporated into the aligners in the first molar region.



Figure 27-14. Intraoral views of the maxillary and mandibular aligners in a patient with mild crowding.

performed in accordance with the instructions of the orthodontist, as written in the treatment planning form.

The company interacts with the orthodontist by way of ClinCheck®, an Internet-based treatment planning tool that relies on 3D-graphical and manipulation techniques. ClinCheck® allows the orthodontist to view a computerized simulation of the entire course of treatment with a level of accuracy and from angles that are not possible using traditional diagnostic methods. Each patient sent into Align Technology, has a "ClinCheck®" file associated with it that is downloaded from the website (www.invisalign.com).

Sequence of Treatment

A course of treatment using the Invisalign® system involves the following steps.

After performing a clinical examination and gathering the necessary diagnostic records, the orthodontist establishes a diagnosis for the patient's malocclusion and determines whether the patient is a candidate for the Invisalign® System. If appropriate, the orthodontist obtains polyvinyl siloxane (PVS) impressions of the pa-

tient's teeth, as well as a bite registration (see below for a detailed description of the impressing-taking technique), and sends them to Align Technology. Polyvinyl siloxane is the impression material of choice because it yields highly accurate impressions that remain stable for as long as three weeks and allows for multiple pours.⁹

The orthodontist submits copies of the lateral cephalogram, the panoramic radiograph (or full-mouth radiographs), and intraoral and extraoral photography. The photographic and radiographic records can be submitted either in hard copy form or over the Internet. In addition, the orthodontist prepares an Invisalign® treatment-planning form (*i.e.* prescription) to specify the goals of treatment and to suggest the specific path of tooth movements required to achieve the desired corrections. Any limitations or compromises should be described as well. This form can be filled out by hand and mailed to the company, or it can be sent electronically via the Align Technology website.

After the company receives the impressions, bite registration, patient records, and the prescription provided by the orthodontist, two sets of dental casts are derived from the PVS impression. The first set of models (termed "scan models") is used to prepare a three-dimensional computer graphic image of the patient's teeth and associated soft tissues. The second set of models is used for validation of the orthodontist's diagnosis and treatment plan by Align Technology clinical staff. The PVS impressions then are archived for purposes of model duplication or replacement.

The technologies involved in the manufacturing of the Invisalign® System are evolving rapidly. At this writing, the scan models (which are poured in die stone rather than in laboratory plaster) are used to produce the three-dimensional computer models that later will be manipulated for simulated tooth movement and ultimately used as the basis for the production of a series of aligners.

The creation of a three-dimensional graphical image of the dental casts is a multi-step process. After the scanning model has been poured and trimmed, the upper and lower models are oriented to each other, first by means of a registration bite typically made from wax or polyvinyl siloxane (*e.g.*, Blue Mousse™), the latter being the preferred material due to its higher accuracy. PVS material has also been successful in that it is less susceptible to heat and cold changes during transport and does not break. Currently, however, most types of wax bites are acceptable for the Invisalign® process.

The patient's bite is taken and registered in centric occlusion. Patients with discrepancies between centric occlusion and centric relation should be told by the

treating orthodontist that the aligners are not intended to resolve such discrepancies; other treatment may be required to address this issue.

Custom-made imaging software then is used to create a digital three-dimensional model of the arch (*i.e.*, the virtual study model) through a proprietary scanning technique. Align's Treat 2.x® software is used to prepare the graphical images for manipulation. Virtual tools in the form of planar and curved cutters that are part of the Treat 2.x® software are used to isolate each tooth within the arch. This procedure in virtual reality is similar to the initial preparation of a tooth positioner in a traditional commercial orthodontic laboratory, a process in which each tooth is removed from the stone or plaster model and prepared for reassembly in final form.

The difference with the digital image, however, is that the reassembly of the teeth in the arch creates an exact replica of the original arch without any deviation in dimensional accuracy. At this point, the trained computer technician manipulates the virtual images, much in the same way that a laboratory technician creates a positioner set-up from an original set of work models. Based on the instructions from the orthodontist, the final occlusion is established virtually by way of the proprietary software, and the "forecast" model representing the final treated occlusion is created, once again in virtual reality.

The next step in the process is to determine the number of intermediate stages (and thus the number of aligners) between the original malocclusion and the final treatment result. The two factors governing the number of treatment stages required are the path of tooth movement and the velocity at which the teeth are to be moved. The maximum velocity of tooth movement currently is 0.20-0.25 mm per tooth per stage. The particular magnitude of the movement is dependent on the nature of the tooth repositioning (*e.g.*, distalization versus simple flaring or space closure). The path of correction will depend on which teeth impede each tooth from moving to its final position. In other words, the movement of a tooth may be delayed until adjacent teeth are moved out of the way.

Obviously, the greater the distance that the teeth need to be moved or rotated and the more complicated the movement path, the greater the number of aligners needed to treat the patient. The number of aligners varies from ten or less for relatively simple problems to fifty aligners or more in complicated malocclusions. Distalization cases, midline discrepancies, and expansion cases typically require more stages than less complicated movements.

Figures 27-15 and 27-16 illustrate a representative sequence in virtual reality of malocclusion correction for a patient requiring 31 sets of aligners. In addition to the forecast model, the entire sequence of tooth movement is established. The gradual changes in tooth alignment can be observed in the six stages shown. Aligners usually are changed every two weeks; treatment for this patient should take 15-16 months to complete. Thus, in addition to the forecast model, the entire sequence of tooth movement is established before the actual treatment begins.

After the forecast model and treatment sequence have been generated, this information is sent over the Internet to the orthodontist, who reviews the forecast model and sequence by way of the ClinCheck® software program. The orthodontist can view the initial malocclusion, the intermediate stages of treatment, and the final forecast model from multiple perspectives, including some views that are not readily obtainable by conventional methods. The orthodontist then approves the treatment plan, or alternatively, may request modifications in the position of specific teeth.

Following the orthodontist's approval of the treatment plan, Align Technology uses the sequence of graphical images combined with computer-aided design and manufacturing (CAD/CAM) in producing the aligners. Specifically, stereolithography (*i.e.*, polymerization of liquid resin with laser technology) is used to make a physical three-dimensional model for each stage out of resin. An aligner is made from each of these physical models. At present, the fabrication of the aligners is performed by hand, a process similar the fabrication of invisible retainers described earlier in this chapter. It is the intention of Align Technology to automate the fabrication process and the trimming of the aligners in the future.

In about half of treatment protocols, it is necessary to add one or more "attachments" to the teeth (Fig. 27-15). Currently, these attachments, which are simply buttons of restorative composite (*e.g.*, Herculite™, Kerr, Orange CA) or light-cure bonding material, are used in instances of significant tooth rotation or for any absolute dental intrusion (*i.e.*, attachments are placed on teeth adjacent to segments being intruded⁵). The attachments provide undercuts that facilitate tooth movement. In some instances, attachments may be used for the retention of the aligners in patients with short clinical crowns. In addition, this methodology has been shown to improve the movement of individual teeth by placing attachments on the teeth adjacent to an extraction site.

The attachments are formed on the teeth using a plas-

tic template (similar to an aligner, but thinner), where each attachment well has been generated in virtual space and will follow the movement of the tooth exactly until the final stage of treatment.

Another issue of significance in many patients with minor to moderate crowding undergoing Invisalign® orthodontic appliance treatment is interproximal reduction (IPR). Because of the nature of the virtual graphical images, Align Technology recommends that as much interproximal reduction (stripping) as possible is carried out prior to time that the polyvinyl siloxane impressions are obtained. By performing reproximation prior to the impression-taking procedure, the precise amount of reduction in tooth width is established before treatment is initiated. Thus, there is no confusion regarding how much stripping actually is required. Miller⁵ advises that if significant interproximal reduction is performed before the PVS impressions, the patient should be given an aligner or invisible retainer to wear at night until the treatment begins.

If interproximal reduction is part of the patient's treatment plan, we recommend that as much stripping as possible is carried out following the the completion of initial diagnostic record taking, preferably during the same appointment. Often aggressive IPR leads to localized gingival bleeding which may compromise the PVS impressions if they are obtained during the same appointment. Thus, stripping ideally should be performed at an appointment separate from the PVS impression appointment.

Reducing the mesiodistal width of the teeth prior to the impression, however, sometimes is not possible without severely compromising the anatomy of certain teeth. In such instances, interproximal reduction may be performed during the course of treatment, instead of before treatment. A reproximation form is sent by Align Technology in these situations, indicating the amount of interproximal reduction required and the stages at which the teeth should be stripped. Significant stripping performed during treatment can result in the necessity of retaking the PVS impressions and remaking the aligners not yet used, obviously incurring added expense and extending the length of treatment. Also, unwanted side effects, such as tooth intrusion can occur when the clinician does not perform interproximal reduction as advised.⁵

Impression Technique

Perhaps the biggest paradigm shift concerning the patient management aspect of the Invisalign® System is the impression-taking technique. Alginate impressions

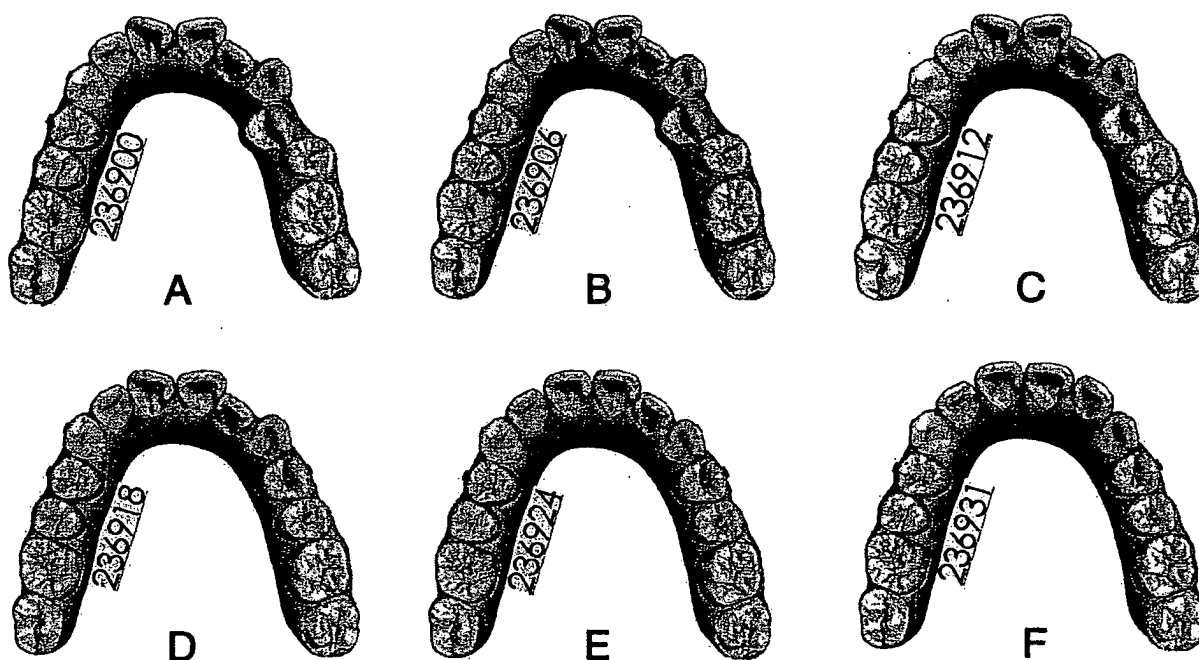


Figure 27-15. Treatment sequence of maxillary correction produced by way of the Treat 2 software. The sequence begins at A, the initial malocclusion and progresses to F, the forecast result. This treatment sequence has 31 stages. The first four numbers next to each image is the patient identification number, The last two numbers indicate the stage of treatment. Attachments can be seen on the facial surfaces of the canines and first premolars. (Images courtesy of Ross J. Miller)

that traditionally have been used by the profession have proven to be inadequate for this procedure. At the time of this writing, Align Technology recommends the use of polyvinyl siloxane (ESPE America, Norristown PA) for generating the model used during the scanning procedure. Polyvinyl siloxane takes far longer to set than does alginate, and the patient should be informed ahead of time about the length of the impression-taking procedure. We also recommend that the patient be draped (e.g., protective drape from a hair salon) in order to protect the clothing of the patient from damage.

The recommended protocol is a two-step technique. The first step involves making the equivalent of a loose-fitting custom tray from a heavy body impression material. The second step is the actual impression itself, made from a light body material that produces a highly accurate negative reproduction of the hard and soft tissue anatomy of the dental arch.

A perforated rim lock metal tray is selected that approximates the size of the patient's dental arch. The tray must be long enough to capture all the teeth in the arch, including second molars and any erupted third molars. In addition, a three-inch square section of Saran Wrap™ plastic film also is cut and set aside for future use.

Prior to beginning the impression procedure, it also

is very important to block out the undercuts of any bridge pontics with wax. Removing PVS trays can be difficult, due to the amount of suction generated. Old crowns with underlying decay and temporary crowns can be pulled off with this material. In order to avoid these problems, the clinician should make sure that any questionable restorations are fixed prior to taking the impressions.

Once the impression material is mixed, the clinician has about two minutes of working time. The tray should be loaded with ESPE Dimension® Penta H tray material, keeping the tip of the dispenser immersed in the material to avoid introducing air bubbles. At the same time, the dental assistant should make sure that the patient's mouth remains isolated and dry.

After the heavy body material has been inserted into the tray, the three-inch square of Saran Wrap™ is placed over the tray and gently smoothed across the impression material. Keeping the Saran Wrap™ in place, the impression is seated fully in the patient's mouth, starting with the posterior region. The tray should be moved slightly from front to back and side to side as the tray is seated to place. Fully seating the heavy body material is crucial, because it is this material that provides the hydraulic pressure necessary to capture the anatomical detail with the light body material. The tray should

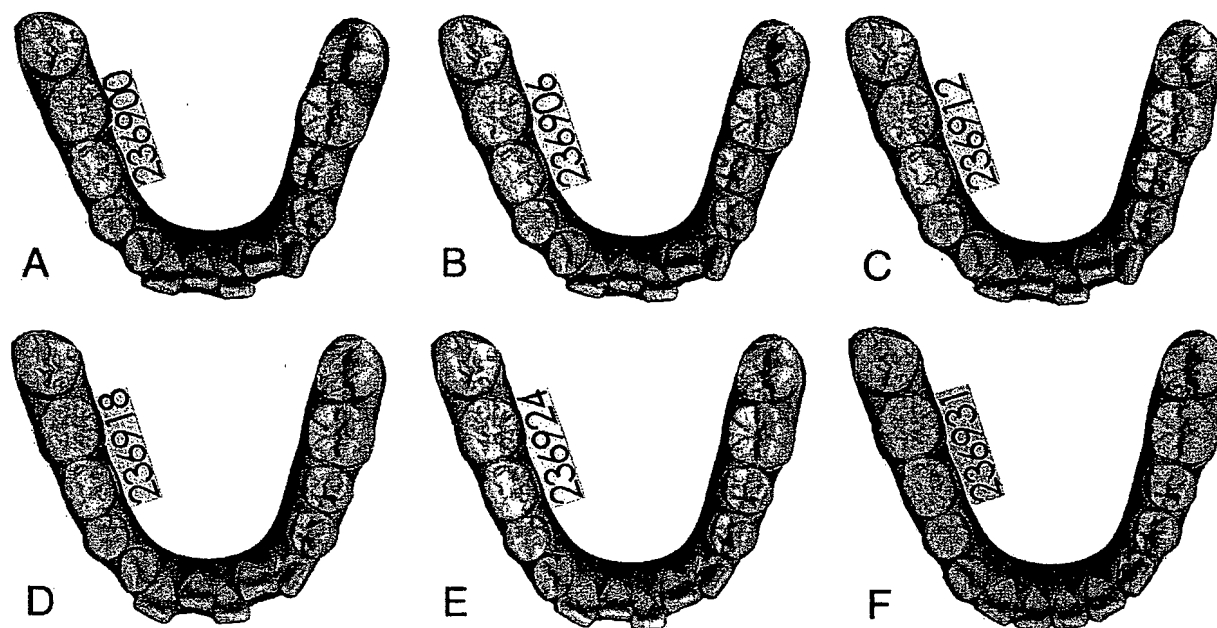


Figure 27-16. Treatment sequence of mandibular correction of the same patient shown in Figure 27-15. The sequence begins at A, the initial malocclusion and progresses to F, the forecast result. This treatment sequence has 31 stages. The first four numbers next to each image is the patient identification number. The last two numbers indicate the stage of treatment. (Images courtesy of Ross J. Miller.)

not be removed from the mouth until the 3½ minute setting time has elapsed, even though the material may appear to have set.

An alternative approach to this technique (which we recommend) is to use the patient's study models for the first step of the procedure. The purpose of the first impression is to create a tray that fits closely to the patient's dental arch; the study model can serve adequately in this regard. The obvious advantage is that the first impression can be obtained without the patient being present, thus saving chair time, and it is easier for the patient.

As the study model is seated into the Saran Wrap™ lined heavy body material, the midline of the study model should be centered in the tray. The model should be seated fully and then moved front to back and side to side. The impression material should be pushed against the study model, as there are no cheeks or lips to do so.

After the impression material has hardened, the study model is removed carefully from the impression tray, guarding against fracturing any of the teeth on the cast. Any excess impression material, especially in the posterior region must be trimmed and removed; otherwise, the tray will not seat in the patient's mouth. The tray always should be placed in the patient's mouth for a preliminary try-in to check for comfort and for the

ability to seat the tray fully, before attempting to take the impression with the light body material. If necessary, the heavy body material can be added to the tray to extend it distally.⁵

The next step in the impression-taking technique involves placing the light-body impression material inside the impression tray containing the heavy body material. The tip of a disposable impression syringe should be cut with scissors to the appropriate size of the opening. A disposable impression syringe should be back-filled with ESPE Dimension™ Garant L light-bodied material, with one-half of a cartridge used per arch. The timer is set for 5½ minutes, with two minutes of working time available. The Saran Wrap™ is removed, and any excess impression material is trimmed from the tray with a sharp instrument. The light-body impression material is loaded on top of the hardened heavy-bodied PVS with the impression gun. Additional light-bodied material is placed in the tray distal to the last molars, as it is difficult to do so in the mouth. Again, it is important not to introduce air bubbles into the material during the loading process.

After the patient's mouth has been suctioned and air-dried thoroughly and before the tray is inserted, the disposable impression syringe should be used to place additional light-bodied material around the gingival margin as well as on the buccal, lingual and occlusal sur-

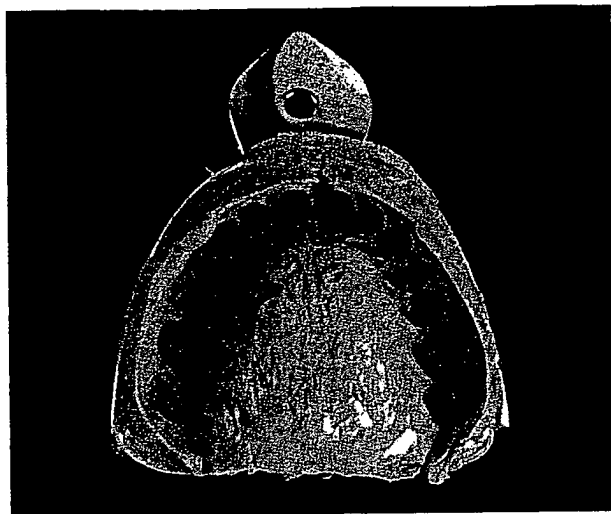


Figure 27-17. Impression made from polyvinyl siloxane. Virtually all of the visible impression is magenta in color, indicating that the light body impression material contacted the teeth and adjacent soft tissue. (Photo courtesy of Ross J. Miller.)

faces of the teeth. In addition, it is very important to place additional impression material by way of the syringe into undercuts of overlapping teeth in patients with moderate to severe crowding.⁵

The syringe tip should be kept in light contact with the teeth. The impression tray then should be reseated in the patient's mouth with light pressure, starting posteriorly and moving forward.

When the timer sounds, the impression tray is removed from the patient's mouth. To aid in tray removal, the clinician should grasp the tray with one hand, and place one finger of the other hand in the patient's vestibule. Having the patient open his or her mouth while rolling the finger in the vestibule will break the seal and facilitate tray removal. The tray is "popped" out of the mouth as the patient opens.

The quality of the impressions then should be evaluated. An accurate impression should show all the gingival margins and the anatomical occlusal surfaces, all in the magenta-colored light-bodied material (Fig. 27-17).

Aside from determining the proper diagnosis and treatment plan, perhaps the most critical step in the fabrication of aligners from the perspective of the orthodontist is obtaining accurate PVS impressions. Attention to detail is extremely important.

CONCLUDING REMARKS

Traditional invisible retainers have had a high level of patient acceptance because they are inconspicuous. The invisible retainer is simple to construct, easy to deliver, and inexpensive. In addition, when the invisible retainer is used as a finishing appliance, minor changes in tooth position also can be obtained. These appliances are not as durable as wire-acrylic retainers, but they provide control over tooth position when worn over the long term.

Combining invisible retainer wear with 3-D technology, as has been developed in the Invisalign® System, provides new opportunities to treat adult patients who otherwise would not consider conventional orthodontic treatment. It must be remembered, however, that the Invisalign® technology is new and evolving constantly. Based on our 30 years of experience routinely using invisible retainers, it is not a question of whether invisible retainers or aligners will move teeth (they will), but rather for which cases this technology is appropriate. It is very important to continue to expand clinical understanding of those cases appropriate for Invisalign® treatment through ongoing clinical studies in university and private practice settings.

REFERENCES CITED

1. Nahoum HI. The vacuum formed dental contour appliance. *New York State Dent J* 1964;9:385-390.
2. Ponitz RJ. Invisible retainers. *Am J Orthod* 1971;59:266-272.
3. McNamara JA, Jr, Kramer KL, Juenker JP. Invisible retainers. *J Clin Orthod* 1985;19:570-578.
4. Abolfathi A. Personal communication, 2000.
5. Miller RJ. Personal communication, 2000.
6. Kesling HD. The philosophy of the tooth positioning appliance. *Am J Orthod* 1945;31:297-304.
7. Sheridan JJ, LeDoux W, McMinn R. Essix retainers: fabrication and supervision for permanent retention. *J Clin Orthod* 1993;27:37-45.
8. Rinchuse DJ, Rinchuse DJ. Active tooth movement with Essix-based appliances. *J Clin Orthod* 1997;31:109-112.
9. Boyd RL, Miller RJ, Vlaskalic V. The Invisalign System in adult orthodontics: Mild crowding and space closure cases. *J Clin Orthod* 2000;34:203-212.
10. Align Technology. Orthodontist workbook: Embark on a whole new movement in adult orthodontics. Santa Clara: Align Technology, 2000.
11. Boyd RL. Personal communication, 2000.

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